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EXAMINER	
MACIAS, CHANDA L	

ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,254	DOW ET AL.	
	Examiner	Art Unit	
	Chanda L. Macias	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-150* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-150* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-150 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-7, 9, 10, 19, and 23, insofar as the claims are drawn to a method for augmenting an immune response in a subject afflicted with cancer, said method comprising administering to the subject a composition comprising at least one ligand for a "pattern recognition receptor molecule" and a delivery vehicle, which cannot be classified because neither the chemical and biologic nature of ligand nor the means by which the immune response is augmented is specified.

Group II. Claims 1-7, 11, 12, 19, and 23, insofar as the claims are drawn to a method for augmenting an immune response in a subject afflicted with infection by a viral pathogen, said method comprising administering to the subject a composition comprising at least one ligand for a "pattern recognition receptor molecule" and a delivery vehicle, which cannot be classified because neither the chemical and biologic nature of ligand nor the means by which the immune response is augmented is specified.

Group III. Claims 1-7, 11, 12, 19, and 23, insofar as the claims are drawn to a method for augmenting an immune response in a subject afflicted with infection by a fungal pathogen, said method comprising administering to the subject a composition comprising at least one

ligand for a "pattern recognition receptor molecule" and a delivery vehicle, which cannot be classified because neither the chemical and biologic nature of ligand nor the means by which the immune response is augmented is specified.

Group IV. Claims 1-7, 11, 12, 19, and 23, insofar as the claims are drawn to a method for augmenting an immune response in a subject afflicted with infection by a bacterial pathogen, said method comprising administering to the subject a composition comprising at least one ligand for a "pattern recognition receptor molecule" and a delivery vehicle, which cannot be classified because neither the chemical and biologic nature of ligand nor the means by which the immune response is augmented is specified.

Group V. Claims 1-7, 11, 12, 19, and 23, insofar as the claims are drawn to a method for augmenting an immune response in a subject afflicted with infection by a rickettsial pathogen, said method comprising administering to the subject a composition comprising at least one ligand for a "pattern recognition receptor molecule" and a delivery vehicle, which cannot be classified because neither the chemical and biologic nature of ligand nor the means by which the immune response is augmented is specified.

Group VI. Claims 1-7, 11, 12, 19, and 23, insofar as the claims are drawn to a method for augmenting an immune response in a subject afflicted with infection by a pathogenic parasite, said method comprising administering to the subject a composition comprising at least one ligand for a "pattern recognition receptor molecule" and a delivery vehicle, which cannot be classified because neither the chemical

and biologic nature of ligand nor the means by which the immune response is augmented is specified.

Group VII. Claims 1-7, 11, 12, 19, and 23, insofar as the claims are drawn to a method for augmenting an immune response in a subject afflicted with infection by a pathogenic prion, said method comprising administering to the subject a composition comprising at least one ligand for a "pattern recognition receptor molecule" and a delivery vehicle, which cannot be classified because neither the chemical and biologic nature of ligand nor the means by which the immune response is augmented is specified.

Group VIII. Claims 1-6, 8, 13-15, 19, and 23, insofar as the claims are drawn to a method for suppressing an immune response in a subject afflicted with an allergy, said method comprising administering to the subject a composition comprising at least one ligand for a "pattern recognition receptor molecule" and a delivery vehicle, which cannot be classified because neither the chemical and biologic nature of ligand nor the means by which the immune response is augmented is specified.

Group IX. Claims 1-6, 8, and 16-23, insofar as the claims are drawn to a method for suppressing an immune response in a subject afflicted with an autoimmune disease, said method comprising administering to the subject a composition comprising at least one ligand for a "pattern recognition receptor molecule" and a delivery vehicle, which cannot be classified because neither the chemical and biologic nature of ligand nor the means by which the immune response is augmented is specified.

Group X. Claims 24 and 25, drawn to a method for inhibiting angiogenesis in a subject comprising administering to the subject an agent capable of inducing an immune response against a specific cell type, or more particularly an endothelial cell, which cannot be classified because the chemical or biologic nature of the agent is not specified.

Group XI. Claims 26-30, insofar as the claims are drawn to a method for stimulating angiogenesis and/or fibrogenesis and/or osteogenesis in a subject with a wound to the skin or a soft tissue, said method comprising administering to the subject a "pattern recognition receptor ligand" and a delivery vehicle, which cannot be classified because the chemical or biologic nature of neither the ligand nor the delivery vehicle is not specified.

Group XII. Claims 26-30, insofar as the claims are drawn to a method for stimulating angiogenesis and/or fibrogenesis and/or osteogenesis in a subject with a bone defect, said method comprising administering to the subject a "pattern recognition receptor ligand" and a delivery vehicle, which cannot be classified because the chemical or biologic nature of neither the ligand nor the delivery vehicle is not specified.

Group XIII. Claims 26-30, insofar as the claims are drawn to a method for stimulating angiogenesis and/or fibrogenesis and/or osteogenesis in a subject with a wound to the bone, or more particularly a bone fracture, said method comprising administering to the subject a "pattern recognition receptor ligand" and a delivery vehicle, which cannot be classified because the chemical or biologic nature of neither the ligand nor the delivery vehicle is not specified.

Group XIV. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-1 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Note: It appears that claim 42 has been erroneously written to depend from claim 30. Here, for the purpose of restriction only and the in the interest of advancing prosecution, it has been presumed that claim 42 should depend from claim 41.

Group XV. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-2 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Group XVI. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-3 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Group XVII. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-4 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Group XVIII. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-5 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Group XIX. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-6 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Group XX. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-7 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Group XXI. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-8 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Group XXII. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-9 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Group XXIII. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-10 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Group XXIV. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-11 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Group XXV. Claims 31-82 and 90-111, insofar as drawn to a composition comprising one or more ligands that binds TRL-12 and one or more antigens, which cannot be classified because the chemical or biologic natures of ligand(s) and/or antigen(s) is not specified to any particularly limiting degree.

Group XXVI. Claims 83-87, 112-121, and 129-140, insofar as the claims are drawn to a method for treating cancer, or for vaccinating a subject against cancer, said method comprising administering to the subject a composition comprising an antigen, a delivery vehicle, and a ligand, which cannot be classified because the chemical or biologic natures of antigen and/or ligand is not specified to any particularly limiting degree.

Group XXVII. Claims 83-85, 88, and 89, insofar as the claims are drawn to a method for treating a disease caused by a viral pathogen, or for vaccinating a subject against said viral pathogen, said method comprising administering to the subject a composition comprising

an antigen, a delivery vehicle, and a ligand, which cannot be classified because the chemical or biologic natures of antigen and/or ligand is not specified to any particularly limiting degree.

Group XXVIII. Claims 83-85, 88, and 89, insofar as the claims are drawn to a method for treating a disease caused by a fungal pathogen, or for vaccinating a subject against said fungal pathogen, said method comprising administering to the subject a composition comprising an antigen, a delivery vehicle, and a ligand, which cannot be classified because the chemical or biologic natures of antigen and/or ligand is not specified to any particularly limiting degree.

Group XXIX. Claims 83-85, 88, and 89, insofar as the claims are drawn to a method for treating a disease caused by a bacterial pathogen, or for vaccinating a subject against said bacterial pathogen, said method comprising administering to the subject a composition comprising an antigen, a delivery vehicle, and a ligand, which cannot be classified because the chemical or biologic natures of antigen and/or ligand is not specified to any particularly limiting degree.

Group XXX. Claims 83-85, 88, and 89, insofar as the claims are drawn to a method for treating a disease caused by a rickettsial pathogen, or for vaccinating a subject against said rickettsial pathogen, said method comprising administering to the subject a composition comprising an antigen, a delivery vehicle, and a ligand, which cannot be classified because the chemical or biologic natures of antigen and/or ligand is not specified to any particularly limiting degree.

Group XXXI. Claims 83-85, 88, and 89, insofar as the claims are drawn to a method for treating a disease caused by a parasitic pathogen, or for vaccinating a subject against said parasitic pathogen, said method comprising administering to the subject a composition comprising an antigen, a delivery vehicle, and a ligand, which cannot be classified because the chemical or biologic natures of antigen and/or ligand is not specified to any particularly limiting degree.

Group XXXII. Claims 83-85, 88, and 89, insofar as the claims are drawn to a method for treating a disease caused by an pathogenic arthropod, or for vaccinating a subject against said pathogenic arthropod, said method comprising administering to the subject a composition comprising an antigen, a delivery vehicle, and a ligand, which cannot be classified because the chemical or biologic natures of antigen and/or ligand are not specified to any particularly limiting degree.

Group XXXIII. Claims 83-85, 88, and 89, insofar as the claims are drawn to a method for treating a disease caused by an pathogenic prion, or for vaccinating a subject against said pathogenic prion, said method comprising administering to the subject a composition comprising an antigen, a delivery vehicle, and a ligand, which cannot be classified because the chemical or biologic natures of antigen and/or ligand are not specified to any particularly limiting degree.

Group XXXIV. Claims 122-128, drawn to a method for preparing a medical device, said method comprising coating a medical device with a composition comprising a ligand, which cannot be classified

because the chemical or biologic natures of device and/or ligand are not specified.

Group XXXV. Claims 141 and 142, drawn to a kit comprising a delivery container, a deliver device, and a ligand, which cannot be classified because the chemical or biologic natures of device and/or ligand are not specified.

Group XXXVI. Claims 143-145, drawn to a method for increasing the healing of bone, said method comprising administering a composition comprising a ligand, which cannot be classified because the chemical or biologic nature of the ligand is not specified.

Group XXXVII. Claims 146-150, insofar as the claims are drawn to a method for relieving mucositis, said method comprising administering a composition comprising a ligand, which cannot be classified because the chemical or biologic nature of the ligand is not specified.

Group XXXVIII. Claims 146-150, insofar as the claims are drawn to a method for relieving serositis, said method comprising administering a composition comprising a ligand, which cannot be classified because the chemical or biologic nature of the ligand is not specified.

Group XXXIX. Claims 146-150, insofar as the claims are drawn to a method for relieving parenchymal injury, said method comprising administering a composition comprising a ligand, which cannot be

classified because the chemical or biologic nature of the ligand is not specified.

Group XL. Claims 146-150, insofar as the claims are drawn to a method for relieving reperfusion injury, said method comprising administering a composition comprising a ligand, which cannot be classified because the chemical or biologic nature of the ligand is not specified.

Group XLI. Claims 146-150, insofar as the claims are drawn to a method for relieving radiotherapy- and/or chemotherapy-associated injury, said method comprising administering a composition comprising a ligand, which cannot be classified because the chemical or biologic nature of the ligand is not specified.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups XIV-XXV and XXXV are products, whereas the inventions of Groups I-XIII, XXVI-XXXIV, and XXXVI-XLI are unrelated because the products of Groups XIV-XXV and XXXV are not specifically used or otherwise involved in the processes of Groups I-XIII, XXVI-XXXIV, and XXXVI-XLI.

The inventions of Groups XIV-XXV and XXXV are patentably distinct, each from the others, for the following reasons:

The inventions of Groups XIV-XXV are compositions comprising one or more ligands that bind a receptor. The inventions of Groups XIV-XXV and XXXV are patentably distinct, each from the others, because each of the ligands of which the different compositions are comprised binds a different receptor, which has a distinct structure and function. For example, the inventions of Group XIV are compositions comprising ligands that bind TRL-1, whereas the inventions of Group XVII are

compositions comprising ligands that bind TRL-4. TRL-1 and TRL-4 are structurally and functionally distinct receptors.

In contrast, the inventions of Group XXXV are kits comprising a container, a delivery device and a ligand. The ligand of which the inventions of Group XXXV is comprised is not necessarily a ligand that binds to any of the receptors to which the ligands of the compositions of Groups XIV-XXV bind.

The inventions of Groups I-XIII, XXVI-XXXIV, and XXXVI-XLI are unrelated, or otherwise patentably distinct methods.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01.

The inventions of Groups I-VII are processes for augmenting an immune response. In contrast, the inventions of Groups VIII and IX are processes for suppressing an immune response. Although the inventions of Groups I-VII are processes for augmenting an immune response, they are processes for augmenting distinct immune responses against different pathogens that cause different diseases; similarly, although the inventions of Groups VIII and IX are both processes for suppressing an immune response, they are practiced to treat different a condition or disease, namely an allergy or an autoimmune disease. The inventions of Group X, on the other hand, are processes for inhibiting angiogenesis, whereas the inventions of Groups XI-XIII are processes for stimulating angiogenesis and/or fibrogenesis and/or osteogenesis. While the inventions of Groups XI-XIII are similarly processes for stimulating angiogenesis and/or fibrogenesis and/or osteogenesis, the inventions of Group XI are processes for treating a wound of the skin or soft tissue, the inventions of Group XII are processes for treating a bone defect, and the inventions of Group XIII are processes for treating a wound to the bone (e.g., a fracture). Groups XXVI-XXXIII are processes for treating different diseases, which are caused by different etiologic or pathogenic factors. The inventions of Group XXXIV are processes for preparing a medical device. The inventions of Group XXXVI are processes for increasing the

healing of bone; and the inventions of Groups XXXVII-XLI are processes for relieving different conditions, infections, or injuries.

The instant specification does not appear to disclose that any of the inventions of Groups I-XIII, XXVI-XXXIV, and XXXVI-XLI are useable together. Therefore, because the inventions of Groups I-XIII, XXVI-XXXIV, and XXXVI-XLI have different purposes or are otherwise materially different processes comprising different process steps that achieve the claimed effect, albeit by administering therapeutic agents the do so by different mechanisms or modes of action, the inventions appear unrelated.

If not unrelated, the inventions of Groups I-XIII, XXVI-XXXIV, and XXXVI-XLI are patentably distinct, each from the others, for the following reasons:

Again, the inventions of Groups I-XIII, XXVI-XXXIV, and XXXVI-XLI have different purposes or are otherwise materially different processes comprising different process steps that achieve the claimed effect, albeit by administering therapeutic agents the do so by different mechanisms or modes of action. Furthermore, where the inventions share the same objective, but are materially different processes, the inventions are distinct because they necessarily have different criteria for success.

Because the inventions of Groups I-XIII, XXVI-XXXIV, and XXXVI-XLI are distinct for these reasons, the search required to examine claims directed to any one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to any other. Furthermore, the inventions of Groups I-XIII, XXVI-XXXIV, and XXXVI-XLI have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter. Because different searches would have to be performed to examine claims directed to the inventions of Groups I-XIII, XXVI-XXXIV, and XXXVI-XLI, an examination of more than one would constitute a serious burden.

Since the inventions of Groups I-XIII, XXVI-XXXIV, and XXXVI-XLI are patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

5. This application contains claims 1-23 and claims 26-30, which are directed to patentably distinct species of the inventions of Groups I-IX and the inventions of Groups XI-XIII, respectively, wherein said ligand(s) are selected from the group consisting of (a) a ligand of TLR-1, (b) a ligand of TLR-2, (c) a ligand of TLR-3, (d) a ligand of TLR-4, (e) a ligand of TLR-5, (f) a ligand of TLR-6, (g) a ligand of TLR-7, (h) a ligand of TLR-8, (i) a ligand of TLR-9, (j) a ligand of TLR-10, (k) a ligand of TLR-11, (l) a ligand of TLR-12, (m) a ligand of a mannan-binding lectin, (n) a ligand of macrophage mannose receptor, (o) a ligand of a scavenger receptor, (p) a ligand of an "endocytic pattern recognition receptor", and (q) a ligand of a mannose-binding receptor.

Each ligand of the above-identified group is structurally and/or functionally distinct from the others because each binds a different receptor or a different group of receptors. Each receptor or each group of receptors to which the ligands bind are structurally and/or functionally distinct, since, for example, each comprises a different amino acid sequence and/or is differently glycosylated, or because each has a different function or role, or because each is expressed by different cells, or subsets of cells.

Furthermore, as it is noted that the ligands are not characterized as having any particular composition or structure, and are only described as binding to particular receptors or groups of receptors, there is a reasonable presumption that none of the above-identified group of ligands shares any particularly identifying structural features.

It is recognized that the claims are directed to processes comprising administering one or more of said ligands; each species of invention, which comprises

administering a different ligand or a different combination of ligands is distinct from the others, since, as explained, each ligand is structurally and/or functionally distinct.

Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of any one member of the genus of ligand will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Therefore, Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one or more ligands selected from the above identified group of ligands to which the claims drawn to the elected invention will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. This application contains claims 31-82 directed to patentably distinct species of the inventions of Groups XIV-XXV, wherein said one or more **ligands** are selected from the group consisting of (a) a glycoprotein, (b) a lipoprotein, (c) a glycolipid, (d) a carbohydrate, (e) a lipid, (f) a nucleic acid, (g) a protein or peptide, and wherein said one or more **antigens** is selected from the group consisting of (a) a virus, (b) a bacterium, (c) a fungus, (d) a protozoan, (e) a parasite, (f) a rickettsial organism, (g) an arthropod, (h) a protein or peptide, (i) a carbohydrate, (j) a lipoprotein, (k) a glycopeptide or glycoprotein, (l) a glycolipid, (m) a lipid, and (n) a tumor cell.

Each antigen of the above-identified group is compositionally and structurally distinct from the others, or is otherwise a different organism or a cell therefrom. In general, a glycoprotein is a conjugate of a protein and a sugar; a lipoprotein is a conjugate of a protein and a lipid; a glycolipid is a conjugate of a lipid and a sugar; a carbohydrate is any of a variety of different compounds, including the starches, sugars, celluloses and gums, which are usually an aldehyde or ketone derivative of a polyhydric alcohol; a lipid is any of a heterogeneous group of fats and fatlike substances characterized by being water insoluble and being extractable by nonpolar solvents; a nucleic acid is a linear polymer of nucleotides; and a protein or peptide is a linear polymer of amino acids.

It is recognized that the claims are directed to compositions comprising one or more of said ligands and/or one or more antigens; each species of invention, which comprises administering a different ligand or a different combination of ligands in combination with a different antigen or a different combination of antigens is distinct from the others, since, as explained, each ligand is structurally and/or functionally distinct and each antigen is compositionally and structurally distinct, or is otherwise a different organism or a cell therefrom.

Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of any one member of the genus of ligands and any one member of the genus of antigens will not provide adequate information regarding any others. Moreover, the search necessary to examine claims directed to

any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Therefore, Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one or more ligands selected from the above identified group of ligands and the one or more antigens selected from the above identified group of antigens to which the claims drawn to the elected invention will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. This application contains claims 83-87, 112-121, and 129-140 directed to patentably distinct species of the inventions of Group XXVI, wherein said cancer is selected from the group consisting of (a) lung cancer, (b) skin cancer, (c) liver cancer (d) bone marrow cancer, (e) leukemia, (f) ovarian cancer, (g) breast cancer, (h) prostate cancer, (i) colon cancer, (j) lymphoma, (k) brain cancer, (l) renal cell cancer, and (m) a cancer of a mesenchymal tissues.

Each species of invention is patentably distinct from the others for the following reasons:

Each type of cancer is etiologically and pathologically distinct from the others, since, for example, each originates from a different type of tissue or cell, or manifests clinically distinct symptoms. Additionally, among many other differences; each type of cancer is associated with different risk factors; each type of cancer is associated with a different set of diagnostically useful molecular markers; each type of cancer differentially expresses proteins that are therapeutically useful in targeting therapeutic agents to the cancer; each type of cancer is more or less responsive to particular therapeutic agents; and each type of cancer is more or less likely to metastasize. Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the examination of claims directed to any one type of cancer requires a unique search that is not required for examination of claims directed to any other type of cancer and will not provide adequate information regarding any other. Moreover, the search required to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search required to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to require Applicant to elect a single species of invention. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the type of cancer to which the claims of the elected invention will be drawn during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that to the extent that claims are drawn to a novel and nonobvious species of invention, the claims are allowable over the prior art but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chanda L. Macias, Ph.D. whose telephone number is (571) 272-9032. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chanda L. Macias, Ph.D.
Examiner
Art Unit 1643

clm
March 27, 2006

STEPHEN RAWLINGS
PRIMARY EXAMINER
ART UNIT 1643